

Appl. No. 10/011,860
Amdt. dated August 17, 2005
Reply to Office Action of June 1, 2005

REMARKS

Applicants have received and carefully reviewed the Office Action mailed June 1, 2005. Claims 49-53 and 55-69 remain pending, with claim 54 cancelled without prejudice. Reconsideration and reexamination are respectfully requested.

In part 3 of the Office Action, claims 61-62 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Specifically, the phrase "positive voltage portion" was objected to as lacking antecedent basis. Applicants have amended claim 61 to remove the offending phrase, and have replaced it with "monophasic waveform", which does have antecedent basis in claim 60, from which claim 61 depends. Claim 62 depends from claim 61 and did not actually contain the objected-to phrase. It is believed that by this amendment, the objection is overcome and should be withdrawn.

In part 5 of the Office Action, claims 49-56, 59-60, and 63-69 were rejected under 35 U.S.C. §102(e) as being anticipated by Patent Application Publication No. 2002/0082658 to Heinrich et al. After careful review of the cited reference, Applicants respectfully disagree.

Claim 54 has been cancelled without prejudice, mooted that portion of the rejection.

With respect to independent claims 49 and 53, Applicants note that the actual (regularized) filing date for the Heinrich et al. application comes after the filing date for the present application. Thus, the Examiner must be relying upon the filing date of the provisional application to which Heinrich et al. claim a benefit in order to treat Heinrich et al. as a §102(e) reference. As the Examiner notes, Heinrich et al. suggest, in Paragraph [0064] of the published application, pulses in the range of 50 and 150 volts. However, it is the Applicants position, as explained below, that this disclosure is not entitled to a date prior to the filing date of the present application.

35 U.S.C. §119(e) states the following:

An application for patent filed under section 111(a) or section 363 of this title for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in a provisional application filed under section 111(b) of this title, by an inventor or inventors named in the provisional application, shall have the same effect, as to such invention, as though filed on the date of the provisional application filed under section 111(b) of this title

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In short, in order for the Heinrich et al. provisional application to have effect with respect to cited aspects of the invention, the provisional application has to have disclosed those cited features in accordance with the first paragraph of section 112.

Heinrich et al., in the provisional application, make reference to therapy for bradyarrhythmia at several places. Reference to amplitude of applied pulses is made as well. On page 4:

According to one aspect of the invention, therapy for bradyarrhythmia may be provided in addition to, or instead of, the tachyarrhythmia therapy. In this embodiment, the system includes an output circuit capable of delivering lower-voltage pulses for transthoracic pacing therapy for bradyarrhythmias. These lower-voltage pulses could be on the order of 100 volts, for example.

Next, on page 5:

Figure 1 illustrates the detection method used during bradyarrhythmia monitoring. If asystole greater than, or equal to, a first predetermined time such as three seconds is detected at A, charging of output capacitors to a predetermined voltage such as 100 volts occurs

In Figure 1:

charging
capacitors to
100 volts to
deliver
transthoracic pacing.

Heinrich et al. attach their invention disclosure forms, which also show only 100 volts. In Appendix A, on page 1:

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AND TREATING VENTRICULAR ARRHYTHMIAS, Medtronic file number P8967.00. This method changes the description of "APPARATUS FOR DETECTING AND TREATING VENTRICULAR ARRHYTHMIAS" from the standpoint that now the device has only one output circuit, capable of delivering high voltage shocks for tachyarrhythmias or 100 volt pulses for transthoracic pacing therapy for bradyarrhythmias.

In Appendix A, on page 2:

P8967.00. In the example described in Figure 1, the device is programmed to monitor for a period of asystole greater than 3 seconds and will withhold pacing until this is detected. Once asystole greater than 3 seconds is detected (A), the device charges the capacitors to 100 volts to prepare to pace (sensing during the charging period to ensure a pace pulse is not delivered on the T-wave) (B), and delivers the transthoracic, monophasic pacing pulse between the active can and the array lead (C). The device immediately recharges to 100 volts (D) and begins to monitor for a heart rate less than 40 bpm. At the end of 1500 ms, in the absence of an intrinsic rhythm, another transthoracic, monophasic pacing pulse is delivered (E). The device immediately recharges to 100 volts and begins the next monitoring cycle, looking for a heart rate less than 40 bpm. The device will continue to pace until an intrinsic heart rate of greater than 40 bpm is detected.

Figure 1 of Appendix 1 is actually the same as for the provisional, and also contains reference to 100 volts. There is no disclosure of any amplitude other than 100 volts for pacing therapy in the provisional application.

Independent claims 49 and 53 recite respective ranges of 25-50 volts and 50-75 volts for cardiac stimulus. In light of the above, the date for the Heinrich et al. publication, at least with respect to the subject matter of these claims and their dependent claims, is the date of actual filing, rather than the date of the provisional application. The present application was filed on November 5, 2001, while the regular application from which Heinrich et al. published was filed on November 21, 2001. Therefore, Heinrich et al. is removed as a reference under §102(e) with respect to these claims, as well as any other claims in the application depending from claims 49 and 53, which includes claims 63-69, which were discussed on pages 3-4, in part 5, of the Office Action. In light of the above, claims 49-53 and 63-69 are believed to be in condition for allowance.

Concerning claims 55, 59, and 60, the Examiner makes use of analysis that assumes some scaling of Figure 5 of Heinrich et al. However, it is clear even from the Examiner's own explanation that the Figures of Heinrich et al. are not drawn to scale. Specifically, referring to Figure 5, there are "12 tic marks" for time period 500, which Heinrich et al. state may be, in an example, 3 seconds long in paragraph 67. This would give 250 milliseconds per tic mark, not 25 as suggested by the Examiner. Next, time period 508 has "9 tic marks" and is suggested by Heinrich et al. as having a duration of 1500 milliseconds, or 166.7 milliseconds per tic mark, not

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the 16.6 milliseconds suggested by the Examiner. The Examiner appears to be stating that the shock would last from line 504 to line 506, or two tic marks.

There are several shortcomings in the rejection. First, it appears that by the suggested manner of finding a pulse duration from the figure, the range disclosed is somewhere between 333 milliseconds and 500 milliseconds, far outside the ranges claimed. Second, Heinrich et al. do not appear to have stated whether their drawings are to scale. However, "When the reference does not disclose that the drawings are to scale and is silent as to dimensions, arguments based on measurement of the drawing features are of little value." MPEP 2125. Third, even if scale was to be inferred, in the present instance, the drawing is self contradictory, and no single scale can be discerned. Finally, it is not apparent how long the actual pulse is – the time of pulse delivery is shown, as is the time that a next event occurs, but there is no disclosure that the pulse lasts until the next event, as the Examiner appears to acknowledge in the rejection by stating "Assuming that recharging 506, and 512 starts immediately following delivery of a pacing pulse 504, 510...".

In light of the above, it is believed that the rejections of claims 55, 59 and 60 should be withdrawn. Furthermore, since Heinrich et al. do not disclose that claimed in parent claim 55, each of claims 50-52 is also allowable over Heinrich et al.

In part 7 of the Office Action, claims 56-58 were rejected as being obvious in view of Heinrich, with the explanation being similar to that given for claims 55, 59 and 60, discussed above. In light of the above discussion with respect to claim 55, it is believed that this rejection should be withdrawn.

In part 8 of the Office Action, claims 62-63 were rejected under 35 U.S.C. §103(a) as being unpatentable over Heinrich et al. in view of U.S. Patent No. 5,391,191 to Holmstrom. Claims 62-63 both depend, indirectly, from claim 49. Therefore Heinrich et al. is not a §102(e) reference against these claims, and the rejection should be withdrawn.

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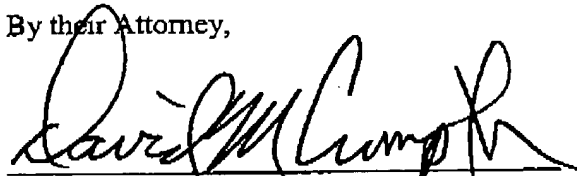
Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Gust H. Bardy et al.

By their Attorney,

Date: 8/17/05



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